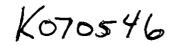
Bio-Rad Laboratories Lyphochek Diabetes Control Summary of Safety and Effectiveness



1.0 Submitter

APR - 2 2007

Bio-Rad Laboratories 9500 Jeronimo Road, Irvine, California 92618-2017 Telephone: (949) 598-1200 Fax: (949) 598-1557

Contact Person

Maria Zeballos Regulatory Affairs Specialist Telephone: (949) 598-1367

Date of Summary Preparation

February 23, 2007

2.0 Device Identification

Product Name:

Lyphochek Diabetes Control

Common Name:

Hematology and Pathology Devices Hematology quality control mixture

Classifications:

Class II

Product Code:

GGM

Regulation Number:

21 CFR 864.8625

3.0 Device to Which Substantial Equivalence is Claimed

Lyphochek Diabetes Control Bio-Rad Laboratories Irvine, California 92618

510 (k) Number: K862186

4.0 <u>Description of Device</u>

This is a lyophilized product prepared from human whole blood containing preservatives and stabilizers.

5.0 Intended Use

Lyphochek Diabetes Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

6.0 Comparison of the new device with the Predicate Device

Lyphochek Diabetes Control claims substantial equivalence to the Lyphochek Diabetes Control currently in commercial distribution (K862186). Both of these controls are manufactured with exactly the same formulation. The only difference between the predicate device and the new Lyphochek Diabetes Control is that new product has claims for Total Hemoglobin and the predicate device does not.

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Bio-Rad Laboratories Lyphochek Diabetes Control (New Device)	Bio-Rad Laboratories Lyphochek Diabetes Control (Predicate Device K862186)	
Similarités			
Intended Use	Lyphochek Diabetes Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	Lyphochek Diabetes Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	
Matrix	Human Whole Blood based	Human Whole Blood based	
Preservatives	Contains preservatives	Contains preservatives	
Form	Lyophilized	Lyophilized	
Storage (Unopened)	2°C to 8°C Until expiration date	2°C to 8°C Until expiration date	
Open Vial Claim	7 days at 2 to 8°C	7 days at 2 to 8°C	
Differences			
Analytes	Claims: Hemoglobin A1C Hemoglobin A1 Hemoglobin F Total Glycated Hemoglobin Total Hemoglobin	Claims:	

7.0 Statement of Supporting Data

Stability studies have been performed to determine the open vial stability and shelf life for this control. Product claims are as follows:

- Open vial Stability: 7 days at 2 to 8°C.
- Shelf Life: 3 Years at 2 to 8°C

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES



Food and Drug Administration 2098 Gaither Road Rockville MD 20850

Bio-Rad Laboratories, QSD c/o Elizabeth Platt Regulatory Affairs Manager 9500 Jeronimo Road Irvine, California 92618

APR - 2 2007

Re: k070546

Trade/Device Name: Lyphochek Diabetes Control

Regulation Number: 21 CFR 864.8625

Regulation Name: Hematology quality control mixture.

Regulatory Class: Class II Product Code: GGM Dated: February 23, 2007 Received: February 26, 2007

Dear Ms. Platt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):	K070546	
Device Name:	Lyphochek Diabetes Contro	ol .
Indications For Use:	quality control material t	trol is intended for use as an assayed to monitor the precision of laboratory analytes listed in the package insert.
Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)
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